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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,942	12/05/2001	Robert J. Hariri	9516-100-999	7788

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,942	HARIRI, ROBERT J.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-24 are pending in the application and under current examination.

Claim Objections

Claims 7, 9, 10, and 12 are objected to because they are drawn to a method for producing new cells and bioactive molecules in the perfused placenta, yet they depend from a method for collecting embryonic-like stem cells from un-perfused placenta. The method steps and the preamble of the claims do not correlate.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, and 10-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These

factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the levels of the skilled in the art, and whether sufficient amount of direction or guidance are provided in the specification to enable one of skill in the art to practice the claimed invention.

Claims 7 and 10 are drawn to stimulating the production of new cells and collecting the produced cells from a perfused placenta lack of residual embryonic-like stem cells. The specification teaches the cell types collected from the placenta perfusates. However, the specification is silent regarding the cells remain in the placenta and their state of differentiation, and thus, fails to teach what type of new cells could be produced. Turning to the knowledge of the skill, it is known that the mammalian placenta comprises at least two highly vascularized membranous envelopes, amnion and chorion, and a small balloon-like sac (chorionic cavity) lying in between the envelopes (Mesh browser). It is known that a mammalian placenta includes a fetal portion (CHORIONIC VILLI) derived from trophoblasts and a maternal portion (DECIDUA) derived from the uterine endothelium. *Ma et al* (Tissue Engineering 1999;5:91-102) teach that the outermost layer of chorionic villi is trophoblast cells, and they are terminally differentiated and lasting no more than about seven days (2nd paragraph, page 92). This seems to be the case for other types of cells in the term placenta such as endothelial cells, *Contractor et al* teach (Cell Tis Res 1984;237:609-17, e.g. abstract) even under nutritional perfusion, oedema and microvillous damage

appeared after *three* hours of placenta perfusion. In view of such, the invention does not appear to be enabled in the absence of clarification of the contradictory evidence found in the references.

Claims 13-21 are drawn to a method of propagating exogenous cells in a placenta bioreactor which has been treated to remove residual umbilical cord blood, comprising perfusing a placenta with an anticoagulant perfusion solution, collecting the perfusate, *removing all remaining viable endogenous cells* from the drained placenta, perfusing the placenta with nutrient perfusion solution, introducing *exogenous cells* into the perfused placenta, incubating the perfused placenta with exogenous cells, and *collecting* propagated exogenous cells from the perfused placenta; wherein the viable endogenous cells are removed by irradiation, such as gamma-radiation, wherein the exogenous DNA is introduced into the cells propagated in the perfused placenta *before* collection, wherein the cells are insect cells or any animal cells.

Given the broadest reasonable interpretation, the claims embrace a method using a mammalian placenta depleted of living cells as a scaffold for culturing and harvesting any type of cells from any origin. In view of guidance provided, the specification teaches draining, perfusing the placenta and collecting the perfusate for embryonic-like cells. The specification teaches generally that the endogenous cells could be removed by irradiation of the perfused placenta with electromagnetic, UV, X-ray, gamma- or beta radiation (paragraph bridging pages 6 and 7), and generally list the growth factors that could be used for propagation of exogenous cells (2nd paragraph on page 7). However, the

specification fails to teach what type of cells are suitable for growing in the placenta, whether a human placenta could be used for propagating insect cells, the dosing regimen for irradiation so that the cells inside the placenta would lost their viability, yet the strength of the placenta tissue remains, and the specification fails to teach what it takes to remove *all* remain viable endogenous cells, and how to collecting the propagated exogenous cells from the placenta after propagation, thus, the specification fails to provide an enabling disclosure for what is now claimed.

In view of the knowledge of the skilled in the art, It is known that the amnionic membrane comprises the basement membrane and stroma, and could be isolated and preserved (*Tseng*, US 6,326,019, abstract), and that the amniotic membrane, particularly the basement membrane side, could be used as a substrate support for cell culture, particularly for epithelial cells, and for neurons of the peripheral and central nervous system. It is also known that the supporting power of the placenta material is not dependent on living cells but mediated by the amniotic matrix (*Tseng*, US 6,326,019, column 4, lines 13-37). In view of the teaching in the prior art, it appears that the components of basement membrane of amnion is the key to culture support, whereas the perfused placenta further comprises chorion and chorionic cavity. It is unknown and the specification fails to teach whether and what type of cells would grow in these areas. *Kleinman et al* (US 4,829,000) teach that the polymerized basement membrane components of the placenta could be used for promoting the growth of a variety of cells (column 4, lines 4-15). However, it is not known in the art the efficiency of

growing exogenous cells in chorion and chorionic cavity, the types and mode of growth of the cells, and how to collect the cells from the various layers and spaces of an intact placenta since the cells may attached to layers of the membranes, how to isolate and efficiently collect them. With regard to collecting the propagated cells, the specification is silent about how to get the cells out of the complex bioreactor, or how to separate the debris with the propagated cells if complete breakdown of the placenta is needed. The specification is silent with regard to these aspects, thus, fails to provide an enabling disclosure to support what is now claimed.

Claims are drawn to growing exogenous cells regardless of cell type and origin in the term placenta including growing insect and any animal cells in a human term placenta. *Kleinman et al* disclose a matrixgel derived essentially from the extract of human placenta and teach that the matrigel could reduce the possibility of immune interaction when it is used in humans (column 4, lines 16-21). Apparently, the mammalian placenta does not appear to have immune privilege. In view of such, it is unknown whether insect cells are compatible with human placenta substances, and would sufficiently grow in the mammalian placenta, and whether any animal cells would grow in a human term placenta.

Claim 16 particularly identifies stem cells as the exogenous cells to be propagated in the cell-free placenta. It is well known in the art that the propagation of stem cells requires particular growth factors and culture condition (IDS/AS). Although the placenta has provided a proper environment for stem cells during the pregnancy, it is unknown and the specification fails to teach

whether the placenta still can support the propagation of stem cells once it is detached from the uterus and has been made cell free. The specification fails to teach whether and how it is advantages to culture the stem cells in the perfused placenta compared to the culture dish routinely used by the skilled in the art. Accordingly, the specification fails to provide an enabling disclosure to support what is now claimed.

The claimed method requires removing viable cells by irradiation. *Badylak et al* teach using various methods for sterilizing submucosal tissue as tissue culture support (abstract). They teach the technique should not adversely affect the mechanical strength, structure, and more importantly, biotropic properties of the tissue, and they teach that strong gamma radiation may cause loss of strength of the sheets of submucosal tissue (column 3, lines 30-49). Considering the complex form of a cavity with multi-layer membranous tissue of the mammalian placenta, the delicate nature of the term placenta, and many cells are deeply embedded in the multiple layers, neither the art of record nor the specification teaches the proper dosing regimen for killing the cells, and whether they are comparable with the doses of sterilization, and whether the dosage would damage the strength and biotropic property of the placenta tissue, and how to remove the cells sine they are not necessarily exposed to the vascular system. Therefore, the specification fails to provide an adequate guidance for the skilled artisan intending to practice the invention.

Claims 11, 12, and 22-24 require transfecting *in situ* the cells in the placenta sac and/or newly propagated cells with a nucleic acid, wherein the

nucleic acid is a viral vector. The specification does not provide any teaching regarding the efficiency of the transfection inside a three-dimensional placenta bioreactor matrix. In view of the prior art of record, *Muhlemann et al* (palcenta 1995 ;16 :367-73) use dual perfusion of human term placental lobules to infect placenta cells with CMV virus, and report that the perfused placenta tissue was exposed to high titers of CMV for up to 9.5 hrs, however, no infected placenta cells were detected by immunocytochemistry, they concluded that human term placenta and the term trophoblast in vitro form an effective barrier to cell-free CMV virus. In view of such, the invention does not appear to be enabled in the absence of clarification of the contradictory evidence found in the references.

In view of the lack of guidance in the specification regarding the method steps of the claimed invention as discussed *supra*, and in light of the decision of the Federal Circuit:

> a specification need not disclose what is well known in the art. See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a **basic** enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, **when there is no disclosure** of any specific starting material **or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art**. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1005 (CAFC 1997) (emphasis added).

Accordingly, in view of the quantity of experimentation necessary to determine the parameters for achieving efficient cell propagation in a perfused term mammalian placenta, in particular for propagating *any* type of cells and cells from *any* origin, the lack of direction or guidance provided by the specification as well as the absence of working examples with regard to *culturing stem cells in the cell-free placenta, removing all remaining viable endogenous cells from the placenta, proliferating new cells of the flushed placenta, genetically engineering placenta cells/newly propagated cells in situ, and collecting the propagated cells from various layers and cavities*, it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

Please note that claims 1 and 6 have not been included in this rejection even though claims 7 and 11 depend from claims 1 and 6. This is because the preamble of claims 1 and 6, and the method steps of claims 7 and 11 do not correlate. For the interest of a compact prosecution, each of claims 7 and 11 has been considered as an independent claim for production of new cells or for genetically engineering placenta cells.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-24 are vague and indefinite because of the claim recitation, "embryonic-like stem cells", the specification fails to define the term, it is unclear

what types of cells the term intends to embrace or exclude, and thus the metes and bounds of the claims are unclear. In view of the Office policy for a compact prosecution and in light of the specification, the term will be interpreted as encompassing "hematopoietic stem cells".

Claims 1-24 are vague and indefinite because of the claim recitation, "collecting embryonic-like stem cells from a placenta" or "propagating exogenous cells in a placental bioreactor". In botany, placenta is the surface of the carpel to which the ovules are attached (Encyclopaedia Britannia); only the mammalian placenta contains the embryonic-like stem cells and can be used as a bioreactor.

Claim 6 recites the limitation "said additional anticoagulant perfusion solution". There is insufficient antecedent basis for this limitation in the claim.

Claims 7, and 10 recite the limitation "said newly produced cells". There is insufficient antecedent basis for this limitation in the claim. Claim 12 recites, "the newly produced cell", which is not consistent with the use of terms in claims 7 and 10. It is suggested to amend the claims to consistently recite "said new cells" or "the newly produced cells" to avoid confusion.

Claim 11 is vague and indefinite because of the claim recitation, "the cells in the placenta". There are at least two types of cells in the mammalian term placenta, cells from cord blood and cells that are part of a placenta structure. It is unclear which cells the claim refers to, thus the metes and bounds of the claim is unclear. For the interest of a compact prosecution, the recitation is interpreted as encompassing both types of cells.

Claims 11 and 12 are vague and indefinite because of the claim recitation, "the cells in the placenta are genetically engineered with exogenous DNA". It is unclear whether the phrase is a method step or a description for the cells in the placenta, and thus, the metes and bounds of the claims are unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Boyse et al* (US 6,461,645), in view of *Belvedere et al* (Stem Cells 2000 July;18:245-51), *Sanders* (US 3,862,002), and *Addison et al* (J Steroid Biochem Mole Biol 1991;83-90).

The claims are drawn to a method of collecting hematopoietic stem cells from a placenta, comprising perfusing a placenta which has been drained of cord blood with an anticoagulant perfusion solution to flush out residual cells and collecting said residual cells and the perfusion solution, wherein the method further comprising separating the stem cells from the residual cells and perfusion solution, preferably by centrifugation, wherein the perfusion is performed by passing the anticoagulant solution into one or both of the umbilical artery and umbilical vein of said placenta, preferably from the maternal part of the placenta,

wherein the perfusion could be continued to maintain the viability of the placenta, wherein the collection is over a period of 24-48 hours after birth. Claim 11 embraces genetically engineer the cord blood cells *after* collecting them from the placenta.

Boyse et al teach obtaining hematopoietic stem and progenitor cells (HSCs) from human neonatal and fetal blood, particularly from the placenta, wherein the cells could be obtained by gravity drainage as well as needle aspiration at the root of the placenta and in the distended surface veins to increase the amount of collection (example 6, and column 51, lines 23-26), wherein the cells are in a solution containing anticoagulant (column 16, lines 46-47), wherein most of the collection was done at the time of birth (within 24 hours, column 14, Section 5.1.1.2.3.6), wherein collected cells are separated and the stem and progenitor cells are obtained (table III). They teach that the placenta blood provides a convenient source for therapeutic transplantation and could be used in gene therapy by transfection with a heterologous (exogenous) gene (abstract and column 5, §2.4). *Boyse et al* do not teach obtaining the HSCs by placenta perfusion.

Belvedere et al teach a method of maximizing the collection of HSCs from the placenta using an apparatus comprising continued collection of blood flow using a device following common UCB collection procedures. They teach that the usual drainage from the umbilical cord/placenta generated limited volume of HSCs, whereas using the pressure device, additional blood volume and a significant increase in the recovery of the fraction of CD34+CD38- progenitor

cells was obtained (abstract). They teach, "IN CONCLUSION, OUR DATA SUGGEST THAT AN OPTIMAL COLLECTION OF UCB CAN SIGNIFICANTLY INCREASE THE AVAILABILITY OF PLURIPOTENT STEM CELLS CAPABLE OF LONG-TERM ENGRAFTMENT" (last paragraph, page 251). *Belvedere et al* do not teach a method of placenta perfusion.

Sanders teaches a method of collecting physiologically (biologically) active placental substances comprising removing residual cord blood (slightly tension to the umbilical cord, column 2, lines 31-38, and lines 45-48) and perfusing the placenta with a perfusion solution containing anti-coagulant (citrate) via umbilical arteries (column 3, lines 48-65). *Sanders* teaches obtaining the trophoblastic tissue strips or whole placenta for culture after perfusion (column 3, lines 14-67). *Sanders* teaches that perfusion could be done in a continuous fashion, harvesting once the desired product reaches a suitable level (column 6, lines 26-36), and various bioactive molecules that could be obtained from the placenta (column 6, lines 56-65). *Sanders* fails to teach obtaining HSCs from the placenta perfusate.

Addison et al teach a method of collecting predinisone and metabolites from isolated and perfused human placenta (abstract), wherein they collect the human placenta five minutes after birth, and use the umbilical artery-vein pair to flush the fetal compartment, and decidual plate cannulae to perfuse the maternal compartment tissue in a circulated manner with a perfusing solution containing anti-coagulant (heparin), and collecting the 6 hr-perfusate samples from the maternal and fetal for analysis at different phases (sections on page 84, and fig. 1). *Addison et al* fails to teach obtaining HSCs.

Evidently, at the time of instant effective filing date, it is known in the art that HSCs could be obtained from the UCB/placenta, and it is desirable and feasible to maximize the HSC collection by needle aspiration and adding pressure to the placenta to obtain additional HSCs having a larger fraction of stem cells; and it is also known in the art the various methods of placenta perfusion with a solution containing an anti-coagulant for collecting biological active substances. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Boyse et al*, *Belvedere et al*, *Sanders*, and *Addison et al*, by combining or substituting the pressure with the perfusion in collection of placenta blood cells with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because it is known that the additional blood from placenta after common procedure not only increased the volume of the collected blood but also increased the quantity of stem cells as taught by *Belvedere et al*, whether the additional blood is obtained by the pressure-device or perfusion or both is the matter of optimization, particularly considering the perfusion procedure does not require the availability of a device. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 1-6, 8, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Boyse et al* (US 6,461,645), *Belvedere et al* (Stem Cells 2000 July;18:245-51), *Sanders* (US 3,862,002), and *Addison et al* (J Steroid Biochem

Mole Biol 1991;83-90), as applied to claims 1-6, 8, 11 above, and further in view of *Bersinger et al* (Reprod Fertil Dev 1992;4:585-8).

Claim 9 is drawn to stimulating the placenta cells to produce bioactive molecules. The combined teachings of *Boyse et al*, *Belvedere et al*, *Sanders*, and *Addison et al* fail to teach stimulating the placenta with a substance.

Bersinger et al teach a method for stimulating the perfused human term placenta to produce pregnancy proteins with late pregnancy serum (table 1).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Boyse et al*, *Belvedere et al*, *Sanders*, and *Addison et al*, by stimulating the placenta cell to produce a desired substance and extracting such with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because it is known as taught by *Sanders* that term placenta contains many valuable substances useful for research or nutritional purposes. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16 and 17 of copending Application No. 10/074,976.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application and that of the cited patent application are each drawn to a method comprising the steps of exsanguinating and perfusing the placenta, and collecting embryonic-like stem cells from said placenta.

The processes of the present application and the cited patent application differ one from the other in the preamble recitation (collecting embryonic-like stem cells vs. culturing an isolated mammalian placenta). However, claim 17 of the cited application clearly recites, "to allow for production of embryonic-like cells". Therefore, the claims of the present and cited patent applications are obvious variants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 6, and 8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-33 of copending Application No. 10/076,180.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application and that of the cited patent application are each drawn to a method comprising the steps of exsanguinating and perfusing the placenta, and continued perfusion for a period of time.

The processes of the present application and the cited patent application differ one from the other in that the claims of the cited application does not recite a step of collecting or separating stem cells. However, the recitation, "to allow for production of embryonic-like stem cells" and the open language, "comprising" embraces further steps of collection and separation, which is disclosed in the specification of the cited application (e.g. paragraphs 0017 & 0018). The processes of the present application and the cited patent application differ one from the other in the preamble recitation (collecting embryonic-like stem cells vs. culturing an isolated mammalian placenta). However, claim 27 of the cited patent application clearly recites, "to allow for the production of embryonic-like cells from said placenta". Therefore, the claims of the present and cited patent applications are obvious variants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Patent Examiner
Art Unit 1632

QJL
May 5, 2003